DEC 2 0 2000

510(k) Summary

CHEMO-AIDE Dispensing Pin

Submitted by:

Judy Kannenberg
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Rt. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:

December 1, 2000

Proposed Device:

CHEMO-AIDE Dispensing Pin

Predicate Device:

B. Braun Chemo Dispensing Pin®

Proposed Device Description:

The Baxter CHEMO-AIDE Dispensing Pin is intended for use by the pharmacist in the preparation and dispensing of chemotherapeutic medications from rubber stoppered vials. It contains a 0.22 micron hydrophobic/oleophobic air-venting filter that minimizes the potential for aerosolization of chemotherapeutic medications during the reconstitution and dispensing process.

The CHEMO-AIDE Dispensing Pin is a standard vented vial access device that can be used with chemotherapeutic agents. It contains a universal vial access spike with female luer adapter and built-in 0.22 micron hydrophobic/oleophobic air-venting filter.

Statement of Intended Use

The Baxter CHEMO-AIDE Dispensing Pin is intended for use in the preparation and dispensing of chemotherapeutic medications from rubber stoppered vials.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed CHEMO-AIDE Dispensing Pin is similar to the currently marketed B. Braun Chemo Dispensing Pin®, cleared under K983794. Both devices are intended for use in the preparation and dispensing of chemotherapeutic medications from rubber stoppered vials. Some key differences between the proposed CHEMO-AIDE and the Braun Chemo Dispensing Pin, lie in the area of the filter. Both devices contain a 0.22 micron hydrophobic air-venting filter. The Baxter CHEMO-AIDE contains a 0.057 square inch polyvinylidene fluoride (PVDF) filter, which is an integral part of the spike body. The Braun Chemo Dispensing Pin contains a .636 square inch filter, which is attached to the spike body. Both devices have a filter retainer, or cover, to protect the clinician from exposure to the chemotherapeutic medications during reconstitution. The filter retainer on the Baxter CHEMO-AIDE is opaque and provides indirect air venting. The Braun filter retainer is transparent with direct air venting.

There is one material in the proposed CHEMO-AIDE Dispensing Pin, which is a material new to Baxter devices. The body of the vial access spike and the filter retainer are composed of a new material (PL 17652) which combines two previously used materials, acrylonitrile butadiene styrene (ABS), Baxter PL 611, and polyester, Baxter PL 1113. This new material has met the requirements of USP physicochemical tests for plastics and biological tests outlined in ISO 10993-1. A summary of the test results is provided is Attachment 8 – Materials.

The remaining materials in the proposed CHEMO-AIDE Dispensing Pin have been previously tested and used in other marketed devices under comparable conditions of use. A table listing materials found in the proposed device, products in which each material has been previously used, and applicable 510(k) numbers is provided in Attachment 8.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

Data regarding the functional performance of the proposed CHEMO-AIDE Dispensing Pin have been generated. A description of the functional testing and results are provided in Attachment 7 - Performance Testing. All data indicate that the proposed device meets or exceeds all functional requirements, supporting its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Ms. Judy Kannenberg
Manager of Regulatory Affairs
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073

Re: K003730
Trade Name: Chemo-Aide Dispensing Pin
Regulatory Class: II
Product Code: LHI
Dated: December 1, 2000
Received: December 4, 2000

Dear Ms. Kannenberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: Not Available

Device Name: CHEMO-AIDE Dispensing Pin

Indication for Use: The proposed Baxter CHEMO-AIDE Dispensing Pin is intended for use in the preparation and dispensing of chemotherapeutic medications from rubber stoppered vials.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cucuzzella
(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices

K003730